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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/746,361 11/08/96 ANDERSON

D 012712-256

EXAMINER

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HM12/0430

GAMBEL P	
ART UNIT	PAPER NUMBER

1644

DATE MAILED:

04/30/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/746361

Applicant(s)

ANDERSON

Examiner

1644

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 2/17/99
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 29-37 is/are pending in the application.
Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 29-37 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of References Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

DETAILED ACTION

1. Applicant's amendment, filed 2/17/99 (Paper No. 18), is acknowledged.
Claim 34 has been amended.

Claims 1-28 have been canceled previously.

Claims 29-37 are pending and being acted upon presently.

2. The text of those sections of Title 35 USC not included in this Action can be found in prior Actions.
This Office Action will be in response to applicant's arguments, filed 2/17/99 (Paper No. 18).
The rejections of record can be found in the previous Office Action (Paper No. 18).
3. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84.
Please see the form PTO-948 previously sent in Paper No. 7.
Formal figures will be submitted upon indication that this application is allowable.
4. Claims 29-32, 34 and 37 stand rejected under 35 U.S.C. § 102(e) as being anticipated by de Boer et al. (U.S. Patent No. 5,747,034) for the reasons of record set forth in Paper No. 18.

Claims 29-37 stand rejected over by de Boer et al. (U.S. Patent No. 5,747,034) in view of art-known procedures and motivation to generate recombinant antibodies (e.g. humanized, chimeric or primatized) for diagnostic and therapeutic regimens as acknowledged on pages 15-20 and 24-27 of the specification (e.g. Newman et al. Biotechnology, 1992) for the reasons of record set forth in Paper No. 18.

Applicant's arguments, filed 2/17/99 (Paper No. 18), have been fully considered but are not found convincing. Applicant's arguments appear to center on the issue that while the referenced B7-1-specific antibodies bind a distinct epitope, this does not support the proposition that the referenced antibodies do not inhibit B7.1/CTLA-4 interactions, as claimed. In support, applicant argues that other prior B7-1 antibodies which bind distinct epitopes inhibit both B7.1/CD28 and B7.1/CTLA-4 interactions, which contrasts with the claimed antibodies which only inhibit the B7.1/CD28 interaction but not the B7.1/CTLA-4 interaction. Therefore, applicant argues that the prior art neither teach nor suggest with an expectation of success B7.-1-specific antibodies which do not inhibit the B7.1/CTLA-4 interaction.

With respect to obviousness, applicant argues that de Boer et al. does not provide sufficient motivation and expectation of success in generating B7.1 -specific antibodies inhibit the B7.1/CD28 interaction. Applicant argues in conjunction with the Draft Manuscript, filed 10/14/97 (Paper No. 10), that B7 binds both CTLA-4/CD28 and CTLA-4/CD28 have a high degree of homology; therefore antibodies that bind B7 and inhibit its interaction with CD28 would also be expected to inhibit interaction with CTLA-4.

Applicant's assertions are not found persuasive given the absence of objective evidence or side-by-side testing to show that the prior art B7-1-specific antibodies do not inhibit the B7.1/CTLA-4 interaction or would be expected to inhibit both CTLA-4/CD28 and CTLA-4/CD2, particularly with respect to the antibodies taught by de Boer et al.. However, given the known exquisite specificity of antibodies and that CTLA-4/CD28 are distinct molecules albeit homologous; one of ordinary skill in the art at the time the invention was made would have been motivated to select recombinant B7.1-specific antibodies as diagnostic and therapeutic agents in treating human immunoregulatory disorders. Also, see Ex parte Raske, 28 USPQ2d 1304 (BPAI 1993) and Gribben et al. (WO 95/3370; 1449).

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

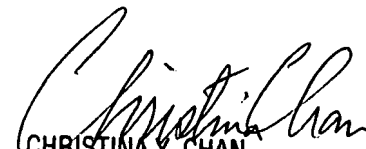
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
April 28, 1999



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